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Public Consultation Paper Reviews Guidelines on Variations to Marketing Authorisations for Medicinal Products The European Commission's Directorate General for Health and Consumers is seeking feedback from stakeholders on the review of guidelines for variations to marketing authorisations for medicinal products. This consultation aims to gather input for a contribution to the review, taking into account scientific and technical progress, as well as recommendations from the Variations Regulation. The European Commission has launched a public consultation regarding the review of Regulation (EC) 1234/2008, focusing on the handling of variations to purely national marketing authorisations. The goal is to simplify and clarify the regulatory framework while ensuring public health. The consultation aims to gather feedback from stakeholders on several key items: * Extending the scope of the Variations Regulation to include purely national marketing authorisations * Adjusting procedures to allocate resources effectively, prioritizing variations with significant impact on public health * Addressing workability concerns and potentially amending the procedure for vaccine authorisation during pandemic settings The Commission has published a public consultation paper, which is available for stakeholders to review and provide input. The final step will involve amending Regulation (EC) No 1234/2008 to include purely national authorisations. The European Commission has adopted a guideline for "veterinary medicinal products" following Article 4(1)(a) of Commission Regulation (EC) No 1234/2008. The regulation aims to examine variations to marketing authorisations for human and veterinary medicinal products, which will apply from January 1, 2010. A draft application form for variation has been developed to facilitate the implementation of the regulations. The guideline outlines the procedures for operation in Chapters II, III, and IV of Commission Regulation (EC) No 1234/2008. The European Commission consulted with Member States, the Agency, and interested parties during the consultation period. A draft guideline has been prepared by DG ENTR after consulting stakeholders, Member States, the Agency, and interested parties. This document outlines the details of various categories of variations to medicinal product marketing authorizations for human and veterinary use. The Commission Regulation (EC) No 1234/2008 mandates the creation of guidelines on these variations. Following months of consultations, a draft guideline has been finalized, but it is not an official position of the European Commission yet. Instead, it serves as a stable document to facilitate stakeholder preparation for the implementation of the Variations Regulation. The guideline will be translated into official languages and submitted to the European Commission for adoption. A new Directive (2009/53/EC) has been published to amend Directives 2001/82/EC and 2001/83/EC regarding variations in marketing authorizations. This revision aims to harmonize rules for all authorized medicines within the EU, making the system clearer, simpler, and more flexible. The implementation of this regulation involves guidelines on various categories of variations, which have been prepared based on public consultations with stakeholders. The goal is to provide a clearer understanding of how variations will be handled under the new regulations. the european commission released guidelines on how to make changes to medical product rules in july 2009. this was part of implementing new regulations on variations, which were laid out in december 2008. the regulation itself was published on december 12, 2008, and outlined the process for examining changes to marketing authorizations for human and veterinary medicinal products. Regulation of pharmaceuticals gets a boost with the revision of the Variations Regulations, aiming to reduce bureaucratic hurdles. The new Commission Regulation has been approved by Member States and is set to replace existing regulations. This development marks a significant step towards simplifying rules for economic operators. The text will undergo scrutiny by the European Parliament and Council before its formal adoption and entry into force. Once in effect, the revised rules are expected to apply one year later, likely around Q4 2009. The European Commission is currently reviewing the Variations Regulations, focusing specifically on the co-decision process. A public consultation has been launched, along with detailed explanations of the consultation process, which can be accessed online. This consultation only addresses the co-decision aspect and does not cover other aspects that can be implemented through comitology. Background information shows that a targeted consultation was conducted in 2006-2007 with industry associations and Member States competent authorities. The current legislation on Variations is available for review. Additionally, the Commission has replaced word-based application forms (AF) with electronic application forms (eAF), offering new features such as data import/export, form population within the form, online access to standardized terms, business rule validation, and support for form validation. The mandatory use of eAF is part of the HMA eSubmission roadmap. Electronic forms and supporting technical documentation can be found below. News updates are available on the Commission's website. The PMS Product User Interface (PUI) has been launched in read-only mode on the PLM Portal, allowing registered users to view CAP data. eAF users now have automatic access to the PUI. Guidance documents and training sessions are available to prepare for registration and navigation of the PUI. An updated v1.26.0.1 Vet MAA eAF is available, featuring a bug fix related to form navigation after finalization. It is recommended to use this latest version for new submissions. Additionally, planned maintenance activities will be performed between April 11th and 16th, during which time the interactive PDF eAFs and PLM Portal web-based eAF will be unavailable. We inform you that the planned maintenance is scheduled to take place from 11th to 16th April 2024, during which time the interactive PDF eAF and the PLM Portal web-based eAF will be unavailable for use. This downtime is necessary for a data load into Product Management Service (PMS) and the simultaneous update of Centrally Authorised Products (CAPs). As announced in December 2023, this process may result in changes to product names, introduction of new medicinal products through splitting, and potential alterations to packages. Vet MAA eAF is available starting February 29, 2024, at 18:00 CET. A minor update has been made to add "United Kingdom (Northern Ireland)" in the Member state selection for sections 2.4.1 and 2.4.4. We recommend using this latest form for new submissions. Note that there is no version number change, and release notes will be published on the eAF webpage. We invite your feedback on your current experience with filling out the interactive PDF eAFs on the PLM Portal for Variations for Centrally Authorised Products (CAPs) and Nationally Authorised Products (NAPs), as well as Initial Marketing Authorisation. Please provide average time spent and resources used to fill in the forms, considering varying procedures may require different time commitments. Your input will help us improve future user experience. You can find the questionnaire at . The survey should take less than 5 minutes to complete, and responses remain anonymous. Please respond by February 29, 2024. If you have any questions or concerns, feel free to post them on the PLM Portal Forum or send an email to plm.valuestream@ema.europa.eu. Updated eAF v1.26.0.0 (Human MAA) and v1.26.0.1 (Vet MAA) are now available. Version 1.26.0.0 Human MAA eAF is ready for immediate use, with a minor bug fix related to Annex 5.19. We strongly recommend using this latest version, which has no version number change and release notes published on the eAF webpage. Version 1.26.0.1 Vet MAA eAF is also available for immediate use, with label and text changes only. The version number has updated from v1.26.0.0 to v1.26.0.1. We recommend using this latest version for all new applications as soon as possible; however, a one-month transitional period will run until January 8, 2024, after which the use of version 1.26.0.1 for Veterinary MAA form will become mandatory. Version 1.26.0.0 has been removed from the eAF website, but users can continue to submit applications using this version until January 7, 2024. Upgrades to the electronic Application Form (eAF) are available, allowing for imports from version 1.26.0.0 into version 1.26.0.1 without manual effort. It's advised not to change the form version during ongoing procedures; if prior to January 8th an updated form is needed, use the previous version instead. Updated release notes are accessible on the eAF webpage. As of November 28, 2023, at 18:00 CET, version 1.26.0.0 of the Variation and Renewal (Human and Veterinary) eAF has been released. A key feature is the ability to select Non-Current terms in the "Pharmaceutical form" lists. It's recommended to use this updated form for new submissions, noting that there is no version number change. Updated release notes are published on the relevant section of the eAF page. Additionally, a new user guide for the eAF for Marketing Authorisation is available on the CMDh website. The DADI Human Variations Forms timeline has also been updated to reflect the UAT timeframe starting September 19th and ending September 30th, 2022. If you need to request a change in the eAF, such as adding a new substance or updating an existing term, please submit your request through the Referential Management Services (RMS) of the SPOR portal with supporting documentation. You can find a step-by-step guide on how to submit change requests in the RMS Web User Manual. Before submitting a change request, ensure you are registered with SPOR and have access to the RMS portal. The SPOR User Registration Manual provides detailed information on registering in SPOR. The EMA will publish the latest versions of technical documents, including Data Exchange Standards and XML Schema Definitions, which enable software developers to process eAF data and build equivalent systems.